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EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/23/2004

rb

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,931

Applicant(s)

HELLMAN ET AL.

Examiner

Lisa V. Cook

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the Office Action mailed June 3, 2003 (Paper #25-filed 10/31/03) is acknowledged. In response to Amendment-H filed therein, claims 25 and 26 have been amended. New claim 27 was added. Currently claims 5, 8, 25, 26, and 27 are currently under consideration.

OBJECTIONS MAINTAINED

Drawings

2. The drawings in this application remain objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the examiner allows the application.

Applicant has deferred corrective action until allowance.

Please Note: Rejections of record not presented below have been withdrawn.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 5, 8, 25, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. Claims 25, 26 and 27 are vague and indefinite in utilizing the term "specifically" because it is not clear as to what Applicant intends to be specific binding. The term "specifically" in claims 25, 26, and 27 is a relative term, which renders the claim indefinite. The term "specifically binding" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In order to obviate this rejection the term should be removed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5, 8, and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claims are directed to "specific binding" however support for the limitation has not been identified in the specification (i.e. page line). Applicant is invited to show support for the limitation in the disclosure.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 5, 8, 25, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hellman et al. (Journal of Bone Mineral Research, Vol.11., No.8., 1996, pages 1165-1175).

Hellman et al. disclose nine monoclonal antibodies against osteocalcin having utility in a two-site capture (non-competitive) assay procedure. Page 1169-1170. The monoclonal antibodies were tested for binding affinity to several forms of human osteocalcin (hOC) and bovine osteocalcin (bOC). See abstract. In one embodiment decarboxylated hOC having Glu at residue 17, 21, and 24 were produced (see page 1168 2nd column 4th paragraph). The antibodies were obtained by immunization and produced in cell lines designated 3G7, 1C4, 1C7, 3H8, 3G8, BD, 2H9, 6F9, and 8H12). See page 1168, 2nd column last paragraph. These cell lines are also employed on page 10 of the instant specification. Both qualitative and quantitative measurements of hOC and bOC were determined. See table 1 and table 3 respectively. The monoclonal antibodies (Mabs) bound the thermally decarboxylated hOC having (Glu) at residues 17, 21, and 24. The antibody combinations taught were useful in detecting the thermally decarboxylated hoc. See abstract. The reference to Hellman et al. disclose antibodies that bind the full structure of osteocalcin with Glu at the 17, 21, and 24 positions; accordingly the antibodies inherently would bind the amino acid sequences set forth in the instant claims.

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Note, the Patent and Trademark Office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference, in the first, place between reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430(CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)).

II. Claims 5, 8, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurihara et al. (US Patent #5,164,483).

Kurihara et al. teach the production of osteocalcin having either of glutamic acid or γ -carboxyglutamic acid at residue 17 and γ -carboxyglutamic acid at residues 21 and 24. Column 3 lines 48-63. The peptides are utilized to generate specific antibodies for human circulating osteocalcin measurements. (For example see column 2, lines 42-56; column 9 line 47 to column 12). Note, the Patent and Trademark Office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference, in the first, place between reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430(CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)).

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III. Claims 5, 8, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hosoda et al. (US Patent #5,506,111).

Hosoda et al. teach the production of antibodies to osteocalcin fragments, and in particular fragments of osteocalcin having residues 1-20 with glutamic acid at residue 17 or having residues 43-49 or having residues 36-49 (column 12-16 and 20-24, and figures 1-3), and the utility of said antibodies in immunoassays for determining osteocalcin. The antibodies specific for residues 1-20 of Glu¹⁷-osteocalcin taught by the reference would inherently bind osteocalcin as instantly disclosed and claimed (open language - having 6-30 or 7-30).

Moreover, antibodies specific for residues 43-49 or residues 36-49 of osteocalcin would inherently bind to osteocalcin having Glu¹⁷ and/or Gla²¹ and/or Glu²¹ and/or Gla²⁴ and/or Glu²⁴. Gamma carboxylation at various sites is discussed in column 2 line 55 to line 65 and column 3 lines 47-55. Note, the Patent and Trademark Office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference, in the first, place between reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430(CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)).

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Response to Arguments

Applicants have not addressed the prior art rejections previously cited under 35 USC 102(b). Accordingly the rejections are maintained. The amendment filed 10/31/03 has been considered but was not found persuasive. Specifically, the claims were modified from open language to closed language regarding the peptide fragment, however the claims are directed to antibodies not the particular fragment being bound. Therefore and reference teaching antibodies which bind the known full length or various fragments thereof read on the instant claims. The art has been applied as such.

6. For reasons aforementioned, no claims are allowed.

Remarks

7. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Koyama et al. (US patent #5,434,245) disclose osteocalcin having either of glutamic acid or γ -carboxyglutamic acid at residue 17 and γ -carboxyglutamic acid at residues 21 and 24. The structure is identified as Glu-OC and presented in figure (I'). Column 1 lines 48-64.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

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Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.



Lisa V. Cook

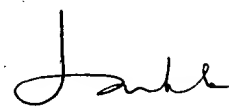
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3/12/04



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3/19/04